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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/441,875	11/17/1999	DAVID E. CHARLTON	CWP-012CN3	5134
21323 7590 07/19/2004 TESTA, HURWITZ & THIBEAULT, LLP HIGH STREET TOWER 125 HIGH STREET BOSTON, MA 02110			EXAMINER DO, PENSEE T	
			ART UNIT 1641	PAPER NUMBER

DATE MAILED: 07/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/441,875	Applicant(s) CHARLTON ET AL.	
	Examiner Pensee T. Do	Art Unit 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 April 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 27-73 is/are pending in the application.
- 4a) Of the above claim(s) 56-73 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 27-55 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 27-73 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Newly submitted claims 56-73 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the newly added device (claim 56) and method (claim 69) fails to require a control site which is distinct from the present invention which requires a control site.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 56-73 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Maintained Rejection(s)

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 27-55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brown, III et al. (US 4,916,056) further in view of Ching et al. (US 5,120,643).

Brown has a test device (10) comprising a casing (14) defining a sample inlet and viewing window (fluid chamber 7) and having disposed therein a test strip comprising a porous fiber matrix 12 (equates the sorbent material which defines a flow

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path for transporting the liquid sample therealong from a sample contact region to a test site and a control site) and a test site (34) comprising an immobilized first protein to a ligand, and a control site (32) comprising immobilized second protein (i.e. an immobilized binder which binds to the conjugate, which conjugate binds to the ligand), and a filter means (22), which device is useful for competitive, sandwich and indirect assays. Chorionic gonadotropin is an explicitly illustrated ligand (example 3). Particles coated with first protein are immobilized within the porous fiber matrix 12 (see col. 4, line 49-col. 5, line 2). The first protein and second protein consists of a variety of monoclonal antibodies or polyclonal antibodies. (See col. 5, lines 54-56). The sorbent means 20 disposed in the casing 14 is for absorbing excess fluid during the use of the assay device. The absorbent means 20 comprises one or more layers of material and is in physical contact with the barrier material 18, when used, or with the reaction matrix 12. (See col. 10, lines 29-46).

However, Brown, III fails to teach colored particulate labels, specifically metal sols.

Ching teaches devices using chromatographically mobile specific binding reagents labeled with colloidal particles such as gold and selenium. Other methods and devices wherein labeled specific binding materials such as colloidal particle labeled and enzyme labeled materials are incorporated on the chromatographic medium of an assay device in a dry form which can be rapidly resolubilized and chromatographically transported along the medium by selected chromatographic solvent. (see col. 10, lines 37-65). The signal is visible to the naked eyes.

It would have been obvious to one of ordinary skills in the art to use the particulate labels taught by Ching in the device of Brown, III since Brown's device is applicable to colorimetric immunoassay. By using the colored labels of Ching, one of ordinary skills in the art could eliminate the step of adding a substrate to produce a visible signal.

Response to Arguments

Since the 103 rejection over Brown III in view of Rosenstein has been withdrawn, no further discussion on the declarations under 37 CFR 1.608(b) to anti-date the Rosenstein patent 5,591,645, is necessary.

The affidavit filed on January 8, 2001 under 37 CFR 1.131 has been considered but is ineffective to overcome the Brown III reference, particularly to overcome the effective filing date of the Brown III reference.

The affidavit fails to show conception and reduction to practice of all features of the claimed invention, particularly it fails to show the "control site", the "filter", the "third binding protein" and "binding analog" (claim 38). Although, the affidavit shows that the inventor had possession of the basic invention prior to March 27, 1987, it fails to show that the inventor had possession of all the claimed features of the claimed invention prior to March 27, 1987. The affidavit only shows reduction to practice the control site. The affidavit also fails to show a control site, which comprises an immobilized binder for binding the conjugate. Thus, figures 6, 7 of Brown III reference are still applicable to the claimed invention.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

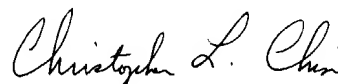
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pensee T. Do whose telephone number is 571-272-0819. The examiner can normally be reached on Monday-Friday, 7:00-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Pensee T. Do
Patent Examiner
July 16, 2004



CHRISTOPHER L. CHIN
PRIMARY EXAMINER
GROUP ~~1800~~ 1641
7/18/04